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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,776	08/23/2000	John Burczak	DEX-0079	2610

7590 11/05/2003

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	**PAPER NUMBER**
1642	18

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/622,776	Applicant(s) Burczak et al
	Examiner Ungar	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 18, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *11, 12, and 16* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *11, 12, and 16* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The Amendment filed September 18, 2003 (Paper No. 17)) in response to the Office Action of June 18, 2003 (Paper No. 16) is acknowledged and has been entered. Claims 16, 11 and 12 are currently being examined.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are maintained:

Claim Rejections - 35 USC § 103

4. Claims 16, 11 and 12 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 16, Section 4, pages 2-5.

Applicant argues that (a)Yamashita et al provide no reasonable expectation of success in monitoring progression from the patient at selected times, (b) Figure 1 shows that serum PLA2 levels in the majority of lung cancer gastric cancer and colorectal cancer patients were actually below the upper normal limit of M-PLA2 levels, thus while there are isolated instances of overexpression of serum M-PLA2 levels in each tissue examined, such varying data between these different carcinomas is not predictive nor suggestive of serum M-PLA2 levels being useful in monitoring other types of cancer such a ovarian or testicular cancer, (c) cell line data was also variable, (d) the Yamashita et al reference fails to teach or suggest the limitations of the claims drawn to monitoring progression, remission or response to therapy of ovarian or testicular cancer.

The arguments have been considered but have not been found persuasive because (a') Applicant is arguing limitations not recited in the claims as currently constituted. The claims are not drawn to monitoring at selected times. Further, for

the reasons of record, Yamashita provide a reasonable expectation of success in that the preponderance of evidence shows that at least a subset of a wide variety of carcinomas from a broad spectrum of tissues overexpresses PLA2 and that for the reasons of record, it would be obvious to use the expression levels of PLA2 to monitor the progression, remission or response to therapy of ovarian or testicular cancer, (a')(b')(d') although the claims are drawn to a method of monitoring progression of ovarian or testicular cancer, the claims are not drawn to monitoring 100% of these patients. It is clear that monitoring 100% of these patients was not contemplated by Applicant because the information in the specification, for example, as drawn to prostate cancer in table 1 shows that the assay does not identify 100% of the patients in advanced stages of prostate cancer. Although Applicant states that the majority of lung cancer, gastric cancer and colorectal cancer patients were actually below the upper normal limit of M-PLA2 levels, Applicant appears to be missing the point. The issue here is not how many patients can be monitored but rather that patients can be monitored. Given that at least a subset of patients for every tumor type tested were found to have elevated PLA2 levels, and that those levels could be used for monitoring for the reasons of record, it would be reasonable to expect that a subset of patients with ovarian or testicular cancer would also have elevated PLA2 levels and that those levels could be used for monitoring for the reasons set forth previously, (c') it is not clear why Applicant is traversing cell culture data. Examiner never brought up the cell culture data because it is notoriously well known in the art that cell culture data cannot be correlated to the *in vivo* condition for a variety of reasons of which Examiner is sure Applicant is

aware. Even if cell culture data could be extrapolated to the *in vivo* condition, given the primary data in Figure 1, the information drawn to the cell culture data is not relevant. Applicant's arguments have been considered but have not been found persuasive and the rejection is maintained. Given the preponderance of the evidence demonstrating the association of carcinomas with PLA2 overexpression, Applicant is invited to submit objective evidence in order to demonstrate that it could not be expected that a subset of all carcinomas would overexpress PLA2 and that overexpression could not be used to monitor progression.

Further, Applicant clarifies that Yamashita et al is not drawn to ELISA assay of PLA2 expression. Examiner appreciates the clarification, apologizes for any inconvenience and points out that it is clear that the inventive step of the instant invention is not drawn to the conventional ELISA assay and as previously stated in Paper No. Paper No. 3, page 6, "The major difference between the RIA of Yamashita et al and ELISA is that RIA detects bound radioactivity and ELISA detects a chromogen that is converted to a colored end product by an enzyme." Both ELISA and RIA are conventional techniques which detect antigen, in this case PLA2 and both are obvious one over the other for the reasons of record.

5. All other objections and rejections recited in Paper No. 16 are hereby withdrawn.

6. No claims allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
November 3, 2003